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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,615	07/26/2001	Marta Gomez-Chiarri	5408	6818
55740 7590 10/23/2009 GAUTHIER & CONNORS, LLP 225 FRANKLIN STREET SUITE 2300 BOSTON, MA 02110				
EXAMINER				
GRASER, JENNIFER E				
ART UNIT		PAPER NUMBER		
1645				
MAIL DATE		DELIVERY MODE		
10/23/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

09/915,615

**Applicant(s)**

GOMEZ-CHIARRI ET AL.

**Examiner**

Jennifer E. Graser

**Art Unit**

1645

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 5, 7, 8 and 16 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CC)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/8/09 has been entered.

Claims 1, 2, 5, and 16 are currently under examination. Claims 7 and 8 were previously withdrawn as being drawn to a non-elected invention.

### ***Rejections which are withdrawn***

2. The former rejections under 35 USC 112, first and second paragraph rejections have been overcome by Applicant's amendments to the claims.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 2, 5, and 16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-20 of U.S. Patent No. 6,913,757. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are drawn to methods of inducing an immune response in an animal which can be fish, bivalves and crustaceans, while the instant claims limit the animal to fish. Additionally, the patented claims specify that the bacteria used in the methods is a live, attenuated *V. anguillarum* which comprises a *mugA* gene comprising nucleotides 1218-2610 of SEQ ID NO: 1 that renders said strain incapable of expressing a functional *mugA* protein (the strain is transformed with a plasmids comprising DNA of interest encoding at least one protein antigen from a pathogen) and this SEQ ID NO: 1 is identical to Applicant's SEQ ID NO: 5 of the instant case. The immersion of fish in a solution comprising the transformed *V. anguillarum* strain is encompassed in 'administering the transformed strain to the animal'. Accordingly, the claims are not patentably distinct from one another.

*Response to Applicant's arguments:*

Applicants argue that the claim language has been narrowed and therefore no longer duplicative of the claims of the '757 patent. This has been fully and carefully considered but is not deemed persuasive for the reasons set forth above. A Terminal Disclaimer should be filed to properly overcome the rejection.

***Specification/Incorporation by Reference***

5. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. See page 26, lines 1-8. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. **The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).**

The disclosure was previously objected to because of the following informalities: the US serial number recited on page 26, line 5, is missing. Applicant improperly amended the specification because it was amended to exclude all reference to Appln. Serial No. 09/915,706 from which the incorporation originally was requested. The specification should be amended to indicate that 10/780,347 is a direct Continuation of 09/915,706 filed 7/26/2001 so as not to confuse that the subject matter to be incorporated was available at the time of filing the instant application.

Appropriate correction is required.

***Sequence Compliance***

6. The CRF/sequence listing filed on 10/8/09 is improper. Applicants cannot incorporate an individual sequence from a prior application with a different sequence number. **A new CRF and paper copy containing SEQ ID NO: 5 must be submitted.**

This will **not** be considered new matter and will be properly entered as it was properly incorporated by reference once the requirements above have been met. However, in order to get the sequence properly entered in the case a new CRF and paper copy must be submitted.

SEQ ID NO: 5 is encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). **APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R. 1.821-25.** Failure to comply with these requirements will result in **ABANDONMENT** of the application under 37 C.F.R. 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

*See additionally the following from 37 CFR:*

**§ 1.825 Amendments to or replacement of sequence listing and computer readable copy thereof. - Appendix R Patent Rules**

***§ 1.825 Amendments to or replacement of sequence listing and computer readable copy thereof.***

(a) Any amendment to a paper copy of the "Sequence Listing" (§ 1.821(c)) must be made by the submission of substitute sheets and include a statement that the substitute sheets include no new matter. Any amendment to a compact disc copy of the "Sequence Listing" (§ 1.821(c)) must be made by the submission of a replacement compact disc (2 copies) in compliance with § 1.52(e). Amendments must also be accompanied by a statement that indicates support for the amendment in the application, as filed, and a statement that the replacement compact disc includes no new matter.

(b) Any amendment to the paper or compact disc copy of the "Sequence Listing," in accordance with paragraph (a) of this section, must be accompanied by a substitute copy of the computer readable form (§ 1.821(e)) including all previously submitted data with the amendment incorporated therein, accompanied by a statement that the copy in computer readable form is the same as the substitute copy of the "Sequence Listing."

**§ 1.821 Nucleotide and/or amino acid sequence disclosures in patent applications. - Appendix R Patent Rules**

***§ 1.821 Nucleotide and/or amino acid sequence disclosures in patent applications.***

e) A copy of the "Sequence Listing" referred to in paragraph (c) of this section must also be submitted in computer readable form (CRF) in accordance with the requirements of § 1.824. The computer readable form must be a copy of the "Sequence Listing" and may not be retained as a part of the patent application file. **If the computer readable form of a new application is to be identical with the computer readable form of another application of the applicant on file in the Office, reference may be made to the other application and computer readable form in lieu of filing a duplicate computer readable form in the new application if the computer readable form in the other application was compliant with all of the requirements of this subpart.** The new application must be accompanied by a letter making such reference to the other application and computer readable form, both of which shall be completely identified. In the new application, applicant must also request the use of the compliant computer readable "Sequence Listing" that is already on file for the other application and must state that the paper or compact disc copy of the "Sequence Listing" in the new application is identical to the computer readable copy filed for the other application.

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/  
Primary Examiner, Art Unit 1645

10/21/09